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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,875	09/26/2001	Joel F. Habener	17633/1235	9674

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,875

Applicant(s)

HABENER ET AL.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-41, 43, 74, 77-79, 81, 83 and 85-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-41, 43, 74, 77-79, 81, 83 and 85-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/05 has been entered.

2. Claims 39-41, 43, 74, 77-79, 81, 83 and 85-108 are pending.

3. Applicant's submission of the Statement of Common Ownership of the WO'784 reference and the instant application, has obviated the previous rejection of claims 39-43, 73 and 76-83 under U.S.C. 102(e) as being anticipated by WO' 784.

The following new ground of rejections are necessitated by the amendment filed 12/27/05

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 39-41, 43, 74, 77-79, 81, 83 and 85-108 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“ An isolated composition comprising at least 30 % nestin-positive...” claimed in claims 39-41, 43, 74, 77-79, 81, 83 and 85-108 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for “An isolated composition comprising...”

The specification and the claims as originally filed only support “ an isolated , nestin -positive human pancreatic stem cells, wherein said cells are at least 30% pure” and “ a pharmaceutical composition comprising said cells .

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 39-41, 43, 74, 77-79, 81, 83 and 85-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9715310 or WO 00/09666 or WO 02/0861107.

WO'310 teaches an isolated nestin-positive human pancreatic stem cells that are not a neural stem cells that can differentiate to form insulin-producing cells. (see entire document, pages 8 ,10, 13 in particular). WO'310 teaches a pharmaceutical composition comprising said cells in cultured media or in PBS, that is a physiologically compatible carrier. (see pages 13 and 14 in particular). WO'310 teaches several methods of isolating pancreatic stem cells comprising steps of removing a pancreatic islet from the donor and separating stem cells from plurality of cells (see overlapping pages 22 -24, in particular). The method of isolating said cells is substantially similar to that used by applicant (see overlapping pages 22-24 in particular). While WO'310 does not specifically teach that these cells are GLP-1R-positive cells, said cells would obviously be GLP-1R-positive cells, since the cell population taught by WO'310 is identical to that claimed in the instant application. It is noted that WO'310 does not explicitly teaches an isolated nestin-positive human pancreatic stem cells, wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed . However, at the time the invention was made one skilled in the art would know how to obtained an isolated population of human pancreatic stem cells wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, preparing an isolated cell composition that would be at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Moreover, it is noted that Applicant acknowledge that at the time the invention was made one skilled in the art will appreciate that a variety of separation strategies based on immunophenotyping methodologies such as surface coated antibody panning, fluorescent antibody tagging for physical isolation, flow cytometric sorting, immunomagnetic bead and

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particle selection and counterselection can be used to obtain isolated distinct population of nestin+ cells (see Applicant's argument mailed on 12/27/05, overlapping pages 19-20 in particular).

Claim 43 is included because the claimed functional limitation would be obvious properties of an isolated cells taught by WO'310 because the referenced cells are the same as claimed and would obviously be able to differentiate to insulin-producing cells. Said insulin –producing cells are the only beta cells to which nestin-positive human pancreatic stem cells can differentiate in the absence of evidence of structural difference.

Claims 77-79 and 105-107 are included because the instant claims are drawn to a product, i.e. to an isolated nestin-positive human pancreatic stem cells. Patentability of the product, i.e. isolated, nestin-positive stem cells does not depend on the method of production or a source from which said cells were isolated in the absence of evidence of structural difference. In re Thrope, 227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

WO '666 teaches an isolated nestin-positive, human pancreatic stem cells that are not a neural stem cells that can differentiate to form insulin-producing cells. WO '666 teaches that said cells is also GLP-1R positive cells (see entire document, Abstract and pages 13, 14, 15 in particular). WO'666 teaches a pharmaceutical composition comprising said cells in cultured media or in PBS, that is a physiologically compatible carrier (see pages 24 and 43 in particular). WO'666 teaches several methods of isolating said cells (see page 18 in particular). It is noted that WO'666 does not explicitly teach an isolated nestin-positive human pancreatic stem cells, wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed . However, at the time the invention was made one skilled in the art would know how to obtain an isolated population of human pancreatic stem cells wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, preparing an isolated cell composition that would be at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure involves only routine skill in the art. *In re Aller*, 220 F.2d 454,456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Moreover, it is noted that Applicant acknowledges that at the time the invention was made one skilled in the art will appreciate that a variety of separation strategies based on immunophenotyping methodologies such as surface coated antibody panning, fluorescent antibody tagging for physical isolation, flow cytometric sorting, immunomagnetic bead and particle selection and counterselection can be used to obtain isolated distinct population of nestin+ cells (see Applicant's argument mailed on 12/27/05, overlapping pages 19-20 in particular).

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Claim 43 is included because the claimed functional limitation would be obvious properties of an isolated cells taught by WO'666 because the referenced cells are the same as claimed and would obviously be able to differentiate to insulin-producing cells. Said insulin –producing cells are the only beta cells to which nestin-positive human pancreatic stem cells can differentiate in the absence of evidence of structural difference.

Claims 77-79 and 105-107 are included because the instant claims are drawn to a product, i.e. to an isolated nestin-positive human pancreatic stem cells. Patentability of the product, i.e. isolated, nestin-positive stem cells does not depends on the method of production or a source from which said cells were isolated in the absence of evidence of structural difference. In *re* Thrope, 227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

WO'107 teaches an isolated nestin-positive human pancreatic stem cells that are not a neural stem cells that can differentiate to form insulin-producing cells. (see entire document, Abstract and pages 8, 10 and 13 in particular). WO'107 teaches a pharmaceutical composition comprising said cells admixed with a physiologically compatible carrier (see page 15 in particular). WO'107 teaches several methods of isolating said cells and emphasizes that said method are well known in the art (see page 8 in particular). While WO'107 does not specifically teach that these cells are GLP-1R-positive cells, said cells would obviously be GLP-1R-positive cells, since the cell population taught by WO'107 is identical to that claimed in the instant application. It is noted that WO'666 does not explicitly teaches an isolated nestin-positive human pancreatic stem cells, wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed . However, at the time the invention was made one skilled in the art would know how to obtained an isolated population of human pancreatic stem cells wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, preparing an isolated cell composition that would be at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure involves only routine skill in the art. *In re Aller*, 220 F2d 454,456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Claim 43 is included because the claimed functional limitation would be inherent properties of an isolated cells taught by WO'107 because the referenced cells are the same as claimed and would inherently be able to differentiate to insulin-producing cells. Said insulin –producing cells are the only beta cells to which nestin-positive human pancreatic stem cells can differentiate in the absence of evidence of structural difference.

Claims 77-79 and 105-107 are included because the instant claims are drawn to a product, i.e. to an isolated nestin-positive human pancreatic stem cells. Patentability of the product, i.e. isolated, nestin-positive stem cells does not depends on the method of production or a source from which said cells were isolated in the absence of evidence of structural difference. In *re* Thrope, 227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

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8. No claim is allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL BELYAVSKIY, PH.D.
PATENT EXAMINER

3/06/06